

**REMARKS**

Reconsideration of the subject application is respectfully requested.

Claims 1-15 and 32-33 are pending in the present application. Claims 1, 2, 7, and 15 are presently being amended.

In the present Office Action, claims 1-15 and 32-33 stand rejected under 35 U.S.C. § 103(a) as unpatentable over references including U.S. Pat. No. 6,251,126 to Ottenhoff, et al. ("Ottenhoff"). In the sole previous Office Action (non-final), claims 1, 2, 4, 5, 14, 16, and 30 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,904,320 to Park, et al. ("Park") and other claims were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of combinations of Park with other prior art not including Ottenhoff. The Examiner did not rely on Ottenhoff for any of those rejections. An Amendment was submitted to overcome the prior art relied upon by the Examiner and the Amendment was entered.

In the final Office Action, the Examiner stated that the rejections are based on a new ground. That new ground is rejection of claims under 35 U.S.C. § 103(a) in which Otterhoff is a significant reference. The present Amendment is by necessity being submitted to overcome the rejections based on Ottenhoff, and was not presented earlier because the prior rejections did not rely on Ottenhoff. Entry of the present amended claims is respectfully requested.

Claims 1, 2, 4, 5, and 14, stand rejected under 35 U.S.C. § 103(a) as being anticipated by Park in view of Ottenhoff (Office Action paragraphs 5-6). The Applicants respectfully traverse the rejection. Park is directed to a sleep apnea therapy device

using dynamic override pacing. Ottenhoff is directed to a method and apparatus for treating sleep apnea involving position sensors on either side of a patient's diaphragm. Claim 1 stands rejected because Park discloses a method of treating sleep disordered breathing comprising the step of applying electrical stimulation of nerves to increase muscle tone of upper airway muscles and Ottenhoff teaches determining the likelihood of a patient being asleep and applying electrical stimulation based on that likelihood. However, neither Ottenhoff nor Park discloses nor suggests delivering therapy at a baseline level, determining the presence of an obstruction, or increasing delivery of therapy to eliminate the obstruction. Claim 1 is being amended to include the steps of delivering treatment at a baseline level if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. Support for these steps can be found at pg. 4, ln. 12 – pg. 5, ln. 4. It is believed that claim 1 is now in condition for allowance. In addition, because claims 2, 4, 5, and 14 depend from claim 1, it is believed that those claims are also in condition for allowance.

The Examiner rejected claims 3, 6, 13, and 32 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Ottenhoff and in view of U.S. Patent No. 5,158,180 to Kallok ("Kallok") (Office Action paragraphs 7-10). Kallok is directed to a method and apparatus for treating sleep apnea using chronic non-tetanic electrical stimulation. Regarding claim 3, the Examiner notes that Kallok teaches that the site of electrical stimulation is within or adjacent to the genioglossus muscle (col. 3, ln. 38-41). With regard to claim 6, the Examiner notes that Kallok teaches a train length of around 50 pulses. Regarding claims 13 and 32, the Examiner notes that Kallok teaches repeated

stimulation in accordance with the detected state of the airway. However, Kallok teaches sensing the tension of the stimulated muscle tissue (col. 2, ln. 24-29) and not determining the presence of an obstruction. In addition, Kallok, like Park and Ottenhoff, does not disclose or suggest delivering therapy at a baseline level, determining the presence of an obstruction, or increasing delivery of therapy to eliminate the obstruction. Claims 3, 6, and 13 depend from claim 1, which is presently being amended. As presently amended, claims 3, 6, and 13 include the steps in claim 1 of delivering treatment at a baseline level if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. None of these steps is disclosed or suggested in Park, Ottenhoff, or Kallok. Therefore, it is believed that claims 3, 6, and 13 are presently in condition for allowance.

In addition, claim 32 depends from claim 7. Claim 7 is presently being amended (discussed below) to include the steps of delivering treatment at a baseline level if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. Again, these steps are not disclosed or suggested by Park, Ottenhoff, or Kallok. It is believed claim 32 is also in condition for allowance.

The Examiner rejected claims 7, 10-12, and 33 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Ottenhoff and in view of U.S. Patent No. 5,207,230 to Bowers ("Bowers") (Office Action paragraphs 11-15). Bowers is directed to a spiral sensor, but does not disclose or suggest where on a patient the sensor should be attached, the use of the sensor relative to sleep disorders, the determination

of sleep disorders, or applying therapy to a patient in any way. Regarding claim 7 in particular, the Examiner notes that Bowers teaches a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles. However, the passage cited by the Examiner (col. 3, ln. 20-23) does not disclose or suggest anything about treating sleep disordered breathing and treating sleep disordered breathing is not disclosed nor suggested anywhere else in Bowers. As presently amended, claim 7 includes the steps of delivering treatment at a baseline level if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. These steps are not disclosed or suggested in any of Park, Ottenhoff, and Bowers. Therefore, it is believed that claim 7 is in condition for allowance.

In addition, regarding claims 10-12, the Examiner cites Bowers (col. 10, ln. 25-30) for periodic mechanical stimulation, periodicity in the order of several seconds, and low mechanical frequency. Regarding claim 33, the Examiner notes that Park discloses stimulation carried out in accordance with a model of Cheyne-Stokes Respiration (col. 7, ln. 41-44). Claims 10-12 and 33 depend from claim 7. Steps of claim 7 are not disclosed or suggested in Bowers, Park or Ottenhoff, including the steps of delivering treatment at a baseline level if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. Therefore, it is believed that claims 10-12 and 33 also are presently in condition for allowance.

The Examiner rejected claims 8, 9, 15, and 31 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Ottenhoff, in view of Bowers and in view of Kallok. (Office Action paragraphs 16-18). Regarding claims 8 and 9, the Examiner notes that Bowers discloses mechanical stimulation by a piezo electric mechanical element and Kallok teaches an element implanted at or near the genioglossus muscle. Claims 8 and 9 depend from claim 7. Steps of claim 7 are not disclosed or suggested in Kallok, Bowers, Park or Ottenhoff, including the steps of delivering treatment at a baseline level if the patient is asleep, determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing treatment until said obstruction is no longer present. It is believed that claims 8 and 9 are presently in condition for allowance.

In addition, regarding claim 15, the Examiner notes that Park in view of Ottenhoff, in view of Bowers, and in view of Kallok discloses an apparatus for treating respiratory disorders comprising a piezo-electric mechanical element (Bowers: col. 3, ln. 20-23), a controller adapted to elicit vibration of the element via an electrical signal (Park: col. 22, ln. 37-38), a real time clock for determining time of day (no cite provided), a position sensor for sensing postural state (Ottenhoff: col. 5, ln. 32-36), and an apparatus adapted for implant at or near the base of the genioglossus muscle (Kallok: col. 3, ln. 38-41). Claim 15 is presently being amended to include the limitation of a detector to detect thoracic impedance changes and the presence of an obstruction, which is not disclosed or suggested by Park, Ottenhoff, Bowers, or Kallok. Support for the limitation can be found at pg. 5, ln. 6 – pg. 6, ln. 5. Therefore, it is believed that claim 15 is in condition for allowance.

Finally, claim 31 had previously been cancelled.

It is believed that the present application is now in condition for allowance. The allowance of claims 1-15 and 32-33 and the early passage to issue of the application are respectfully requested.

Respectfully submitted,  
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